K023776

510(k) SUMMARY

JAN 2 3 2003

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
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P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: November 11, 2002

TRADE OR PROPRIETARY NAME: XENO® III DENTAL ADHESIVE

CLASSIFICATION NAME: Resin tooth bonding agent (872.3200)

PREDICATE DEVICES: Prime & Bond™ NT™ Nano-Technology K982394
Light Cured Dental Adhesive

DEVICE DESCRIPTION: XENO® III DENTAL ADHESIVE is a single step self-etching dental adhesive designed to bond direct light-cured composite restorative materials to enamel and dentin.

INTENDED USE: XENO® III DENTAL ADHESIVE is indicated as a dental adhesive for direct light-cured composite restorative materials.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in XENO® III DENTAL ADHESIVE have been used in marketed devices or have been found to be safe for dental use.

XENO® III DENTAL ADHESIVE was evaluated for biocompatibility and found acceptable.

We believe that the prior use of the components of XENO® III DENTAL ADHESIVE in legally marketed devices, the biocompatibility data provided, and the performance data provided support the safety and effectiveness of XENO® III DENTAL ADHESIVE for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2003

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
570 West College Avenue
York, Pennsylvania 17404

Re: K023776
Trade/Device Name: Xeno III Dental Adhesive
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 11, 2002
Received: November 12, 2002

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K023776

Device Name: **XENO® III DENTAL ADHESIVE**

Indications for Use:

Dental adhesive for direct light-cured composite restorative materials

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Kevin Mulloy for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023776